K071066

510(k) Summary – SpyCatch™ Stone Retrieval Basket

1. Submitter:

JUN 29 2007

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752

Contact: Neil Kelly
Regulatory Affairs Specialist
Date Prepared: March 19, 2007

2. Device:

Trade Name: SpyCatch™ Stone Retrieval Basket
Common Name: Dislodger, Stone, Biliary
Regulation Number: 876.5010
Regulation Name: Biliary catheter and accessories
Classification: Class II
Product Code: LQR

3. Predicate Device:

Boston Scientific Corporation's Biliary Flat Wire Baskets, K925879

4. Device Description:

The proposed SpyCatch is a stone retrieval device designed to pass through the working channel of a scope with a working channel of ≥1.1mm and retrieve stones inside the biliary duct.

5. Indications for Use:

The SpyCatch Stone Retrieval Basket is used endoscopically to entrap and remove stones from the Biliary system. The SpyCatch Stone Retrieval Basket is designed to be used through the working channel of a delivery device accessing the Biliary system.

6. Technological Characteristics:

The SpyCatch™ Stone Retrieval Basket represents the same fundamental scientific technology as the currently marketed Biliary Flat Wire Baskets, K925879.

7. Performance Data:

Design Verification testing has been conducted to confirm that the proposed basket meets its intended use.

8. Conclusion:

Boston Scientific Corporation has demonstrated that proposed SpyCatch Stone Retrieval Basket is substantially equivalent to the currently marketed Biliary Flat Wire Baskets, K925879.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUN 29 2007

Mr. Neil Kelly
Regulatory Affairs Specialist
Endoscopy
Boston Scientific Corporation
100 Boston Scientific Way
MARLBOROUGH MA 01752

Re: K071066
Trade/Device Name: SpyCatch™ Stone Retrieval Basket
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: LQR
Dated: May 25, 2007
Received: May 29, 2007

Dear Mr. Kelly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K071066

Device Names:

SpyCatch Stone Retrieval Basket

Indications for Use:

The SpyCatch™ Stone Retrieval Basket is used endoscopically to entrap and remove stones from the biliary system. The SpyCatch Stone Retrieval Basket is designed to be used through the working channel of a delivery device accessing the biliary system.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K071066